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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/586,285	07/13/2006	Fenglin Chen	U 016354-9	3074

140 7590 05/21/2008

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EXAMINER	
COOK, LISA V	
ART UNIT	PAPER NUMBER
1641	
MAIL DATE	DELIVERY MODE
05/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,285	CHEN, FENGLIN	
	Examiner	Art Unit	
	LISA V. COOK	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/10/07 & 9/8/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Status

1. Currently, claims 1-18 are pending and under consideration.

Priority

2. If applicant desires priority under 35 U.S.C. 120 to application number PCT/CN04/00134 filed 2/20/2004 based upon previously filed applications, specific reference to the earlier filed application must be made in the instant application. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

This should appear as the first sentence of the specification following the title, preferably as a separate paragraph unless it appears in an application data sheet. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression *"now Patent No. _____" should follow the filing date of the parent application.* If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application.

If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c).

The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

3. The instant application should be updated to include the correct status of application number PCT/CN04/00134 on page 1 of the specification. Please include Patent Application Number PCT/CN04/00134 filed 2/20/2004 to the specification.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

5. The information disclosure statements filed 9/8/06 has been considered as to the merits prior to first action.

6. The information disclosure statements filed 8/10/07 has been considered as to the merits prior to first action.

Specification

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification. The disclosure is objected to because of the following informalities:

I. The first page of the specification is not numbered. Appropriate correction is required.

Abstract

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

9. The instant abstract includes legal phraseology "comprising". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *Claims 13-14 are rejected because they are dependent on either claim 7.*

A. Claims 1 and 15 are vague and indefinite is reciting methods that are "characterized by" because it is not clear as to what the claims will encompass. It is suggested that the claims utilize the appropriate transitional language, either "comprising" or "consisting of" in order to obviate this rejection. Please correct.

B. Claims 2, 6, 7, and 16 are vague and indefinite because the process by which the fibronectin is produced (derivation) does not further limit the methods of utilizing fibronectin or kits which comprise fibronectin. The "derived" language is ambiguous because it does not further limit the claims. It is suggested that the actual structural feature that the derivation imparts to the fibronectin be added to the claim in order to further limit. However, Applicant is cautioned not to add new matter into the claims. Appropriate correction is required.

C. Claims 3-5, 8-12 and 17-18 are vague and indefinite because they fail to further limit the independent claims. It appears that Applicant intends to recite method of isolating a product. However the instant claims are drawn to methods of utility/detection and kits. It is suggested that the claims be modified in order to be given patentable weight. Please correct.

D. Claims 2, 6, 7, and 16 recites the phrase "fragments thereof", however it is unclear how to define fragments that are considered to relate to the recited detection method and kits in the instant claims. The specification does not teach examples of "fragments thereof". Therefore the phrase "fragments thereof" is vague and indefinite because the characteristics needed to determine whether an unknown could be considered immunologically detectable while being a "fragment thereof" is unknown. The specification neither discloses a definition for "fragments thereof", nor does it teach a requisite amount of retained qualities needed or characteristics necessary to determine phrase "fragments thereof". Accordingly the claims are unclear and the term should be removed.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2-5, 7-14, and 16-18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *(claims 3-5, 8-14, and 17-18 are rejected as being dependent on either claims 2, 6, 7, or 16).*

Claims 2, 6, 7, and 16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 2, 6, 7, and 16 are drawn to "fragments thereof". The written description is not commensurate in scope with the claims drawn to "fragments thereof". Neither the specification nor the claims teach how to define or obtain "immunologically detectable fragments thereof".

There is no guidance as to what the "fragments thereof" or how much derivation can occur while retaining the required product characteristics necessary to be considered a "fragments thereof", reading on the instant claims. There is no guidance as to what the "fragments thereof" are or which "fragments thereof" can or cannot be used in the method being claimed. The specification does not include structural examples of "fragments thereof".

Thus, the resulting recited "fragments thereof" could result in a complexes not taught and enabled by the specification. *Vas-Cath Inc. V. Mahurkar*, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

The skilled artisan cannot envision the detailed structure of the "fragments thereof", thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore the full breadth of the claims, do not meet the written description provision of 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Ogasawara et al. (Lancet, Vol.347, 4/27/96, pages 1183-1184).

Ogasawara et al. teach methods measuring antinuclear antibodies (ANA) as a predictive measure in recurrent aborters. Antinuclear antibody levels of 225 women with a history of two consecutive first-trimester miscarriages were compared to 740 control women with healthy first-trimester pregnancies. It was concluded that ANA are associated in some way with miscarriages. See pages 1183-1184.

II. Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by Kwak et al. (Journal of Reproductive Immunology, 1995, Vol.28, pages 175-188).

Kwak et al. teach methods measuring antinuclear antibodies (ANA) as a predictive measure in recurrent abortion. The patients were infused intravenously with immunoglobulins (treated). See abstract and page 177 - section 2.2. Pre-treatment samples as well as post-treated samples were analyzed. See pages 178-179 and figure 6 on page 184 for example. Elevated ANA measurements in women are taught to be linked to infants with congenital AV heart blockage. The researchers further disclose that ANA should be measured in women with recurrent spontaneous abortions or fetal losses of unknown etiology. See page 186- 1st paragraph.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

III. Claims 2-6 are rejected under 35 U.S.C. 103(a) as being obvious over Ogasawara et al. (Lancet, Vol.347, 4/27/96, pages 1183-1184) in view of Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118).

Please see Ogasawara et al. (Lancet, Vol.347, 4/27/96, pages 1183-1184) as set forth above.

Ogasawara et al. (Lancet, Vol.347, 4/27/96, pages 1183-1184) differs from the instant invention in not specifically teaching the measurement of Chromosome No.2.

However, Bernasconi et al. teach the evaluation of spontaneous abortion in a 36 year old normal healthy female. The patient had five spontaneous abortions during the first three months of pregnancy. Cytogenic investigation disclosed a female karyotype with isochomosomes of 2p and 2q replacing two normal chromosomes 2. It appeared that chromosome No.2 was important in the patient's pregnancies. Absent evidence to the contrary the measurement of Chromosome No.2 is deemed obvious given the teaching of the prior art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure Chromosome No. 2 as exemplified by Bernasconi et al. in the method of Osgasawara et al. because Bernasconi et al. taught a link between spontaneous abortion and this chromosome. One of ordinary skill in the art would have been motivated to measure Chromosome No.2 as a means for understanding why the abortions may be occurring and thereby possibly treat and prevent spontaneous abortions.

IV. Claims 7-12 and 16-18 are rejected under 35 U.S.C. 103(a) as being obvious over Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) in view of Foster et al. (U.S. Patent #4,444,879).

Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) differ from the instant invention in not specifically including isolated chromosome No.2 in kit embodiments.

However, kits are well known embodiments for assay reagents. Foster et al. (U.S. Patent #4,444,879) describe one example. In their patent kits including the reactant reagents, a microplate, positive controls, negative controls, standards, and instructions are taught. The kits include labeled antibodies (claim 14). See column 15 lines 22-23. The reagents are compartmentalized or packaged separately for utility. See figure 6, and column 15, lines 10-34.

It would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to take the Chromosome No.2 reagent of Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) and format it into a kit because Foster et al. taught that it is convenient to do so and one can enhance sensitivity of a method by providing reagents as a kit.

Further, the reagents in a kit are available in pre-measured amounts, which eliminate the variability that can occur when performing the assay. Kits are also economically beneficial in reagent distribution.

V. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being obvious over Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) in view of Foster et al. (U.S. Patent #4,444,879) and further in view of Maggio (Immunoenzyme technique I, CRC press © 1980, pages 186-187).

Please see Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) in view of Foster et al. (U.S. Patent #4,444,879)as set forth above.

Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) in view of Foster et al. (U.S. Patent #4,444,879) differ from the instant invention in not specifically teaching antigen immobilization (bound to solid support or carrier).

However, Maggio disclose enzyme immunoassays wherein either the antigen or antibody is immobilized onto a solid phase. The solid phase can be particles, cellulose, polyacrylamide, agarose, discs, tubes, beads, or micro plates (micro titer plates). See page 186. The reagents can be bound to the solid support by covalent linkage or passive adsorption (non-covalent means). See page 187 1st paragraph. Maggio taught that solid supports such as test strips "are very convenient to wash thereby reducing labor in assay procedures". Page 186, last line.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to immobilize antibodies on solid support surfaces as taught by Maggio in the kits having utility in the assay methods including Chromosome No.2 as exemplified by Bernasconi et al. (American Journal of Human Genetics, 1996, Vol.59, No.5 pages 1114-1118) in view of Foster et al. (U.S. Patent #4,444,879) because Maggio taught that reagent immobilized solid support "are very convenient to wash thereby reducing labor in assay procedures". Page 186, last line. Absent evidence to the contrary the immobilization of reagents is deemed and obvious modification taught by the prior art.

Remarks

14. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Jones (Acta Endocrinologica, 1975, Vol.78, No.Suppl94, pages 376-404, Abstract Only) disclose semen correlation to infertility.

B. Aoki et al. (American Journal of Reproductive Immunology, 1993, Vol29, pages 82-87) teach methods measuring antinuclear antibodies (ANA) as a predictive measure in recurrent abortion. The patients were treated and ANA measurements were compared to control. See entire reference.

15. For reasons aforementioned, no claims are allowed.

16. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lisa V. Cook
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4/28/07

/Lisa V. Cook/
Examiner, Art Unit 1641